

**REMARKS**

This Amendment is filed alongside a Request for Continued Examination in response to the Office Action mailed on April 29, 2008. In the present Amendment, claims 1, 7, 10, and 16 are amended. Claims 1-19 are currently pending. In light of the following remarks, the applicant requests withdrawal of the pending rejections and advancement of this application to allowance.

***Preliminary Matters***

The applicant has amended independent claims 1, 7, 10, and 16 herein to clarify that the data downloaded into a pump includes individualized, patient-specific data items. Support for these amendments can be found at least at page 5, lines 1-14, which reflects that at least certain data items (e.g. patient age and weight) to be provided to a pump relate to operation of the pump with respect to a specific patient, rather than a class of patients. Additional support can be found at page 23, line 21, through page 24, line 24. These claim amendments are intended to be clarifying only, and reflect the originally intended scope of the claims.

***Claim Rejections – Double Patenting***

In the Office Action, claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending application having serial number 09/631,000. The applicant observes that claim 20 of both cases is presently canceled, and assumes that the rejection persists as to currently pending claims 1-19 of this case. The applicant further observes that neither of these applications is yet allowed, and that therefore this provisional rejection should not impede allowance of the claims in the present application if deemed otherwise allowable. M.P.E.P. § 822.

***Claim Rejections - 35 USC § 103*****A. Claims 1-3 and 6**

In the Office Action, claims 1-3 and 6 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,788,669 to Peterson in view of U.S. Patent No. 5,713,856 to Eggers in view of Official Notice. The applicant

respectfully traverses this rejection and does not concede the characterizations of the cited references or the pending application set forth in the Office Action.

Independent claim 1 recites, among other elements, that at least some of the program data batch-downloaded into memory on a pump are individualized, patient-specific data items. The applicant asserts that no combination of the cited references and the Official Notice can teach or suggest at least this element, and therefore no combination of the references can result in the claimed combination.

In an example contrast to the independent claims, none of the asserted prior art references teach or suggest batch-downloading of data items that include individualized, patient-specific data items. Peterson fails to teach or suggest batch-downloading to a pump data items including individualized, patient-specific data items. As cited in the Office Action at page 2, Peterson discloses delivery of fluid according to a specific therapy (col. 1:20-21); however, Peterson therefore allows therapy-specific pump operation, not individualized, patient-specific pump operation. As illustrated in Peterson, pump programs downloaded to a pump are held separately from a trace table, which contains patient and pump identifying information. See Peterson, Figure 2; col. 6:41-65. Peterson therefore stores patient information on a computer separately from anything transmitted to a pump, and does not provide for batch download to a pump of individualized, patient-specific data items as claimed.

Eggers also fails to teach or suggest batch-downloading to a pump data items including individualized, patient specific data items. The Office Action indicates that Eggers discloses batch downloading of patient-specific data because “dosages are in fact patient-specific data. For example a toddler has a dosage requirement of a medicine which is usually different from an adult.” Office Action at page 9. The applicant respectfully disagrees with this characterization of Eggers and the claim for a number of reasons. First, dosages for adult and pediatric patients do not correspond to individualized, patient-specific data. A generalized adult dose does not distinguish among different doses required for different adult individuals, and therefore dosages in general cannot satisfy this aspect of the claim. Second, Eggers does not in fact disclose batch download of data including individualized, patient-specific dosages; the referenced portion of Eggers relates instead to “dosage units and dose limits”. Eggers, col. 10:65-66.

These references relate to global dosing limits and units of measure, and are not based upon the particular patient or even the type of patient using the pump. In fact, Eggers discloses that user programming of actual rate/dose information is required for each specific patient, which indicates that individualized, patient-specific data items are not batch-downloaded to the pump. Eggers, col. 16:30-45. Third, and with respect to the toddler/adult distinction made in the Office Action, Eggers contains a pediatric drug calculating mode that allows a user to edit dosage calculations *after* a generalized dosage is transmitted to the pump (Eggers, col. 16:59-64); Eggers would therefore not download separate dosage-related items for pediatric and adult patients, even if such different programs correspond to individualized, patient-specific data (which they do not, as previously explained).

Further with respect to Eggers, the Office Action indicates that, at least with respect to claim 7 and related claims,<sup>1</sup> “the step of downloading the library of data wherein each drug library can be customized for each user is equivalent to batch downloading data for a specific patient.” Office Action at p. 7. The applicant respectfully disagrees with this characterization as well. The portion of Eggers cited in the Office Action (col. 10:62 to col. 11:7) refers not to data items specific to a user, but information that “can be used to perform drug calculation based infusions.” Eggers explicitly requires that patient-related drug calculations and entry of resulting dosing variables be performed on a pump, not stored as a separate set of data items. Eggers, col. 16:16-32 (The user must enter the drug amount, diluent volume, patient weight. . .To enter values for these parameters, the user must press the softkey. . .); col. 16:30-45. Eggers therefore describes a system in which a user can create and download to a pump customized libraries of these general information items, and later use the pump to individualize certain parameters to a patient. Eggers therefore does not relate to batch download of individualized, patient-specific data items.

Furthermore, and as stated in the previous response, the Official Notice does not relate to batch downloading the plurality of data items into memory within the pump, at

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<sup>1</sup> Although, in the Office Action, this position is presented with respect to claim 10, it is believed to be applicable to each of the claims in the application.

least some of the data items batch downloaded into memory being individualized, patient-specific data items as set forth in the claims.

Based upon the above discussion, the applicant respectfully asserts that no combination of the cited references and the Official Notice teaches or suggests each of the elements of these independent claims. Likewise, claims 2-3 and 6 depend from claim 1, and therefore inherit the limitations of that claim. Applicants respectfully request reconsideration and withdrawal of the rejection of these dependent claims as well.

**B. Claims 7-20**

In the Office Action, claims 7-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Peterson in view of Eggers, in view of Official Notice and in view of U.S. Patent No. 6,714,969 to Klein. Applicants respectfully traverse this rejection.

Analogously to claim 1, independent claims 7, 10, and 16 each require the capability of batch downloading a plurality of data items into memory within the pump, where at least some of the data items are individualized, patient specific data items. The applicant asserts that no combination of the cited references and the Official Notice can teach or suggest at least this element, and therefore no combination of the references can result in the claimed combination.

As discussed with respect to claim 1, Peterson, Eggers and the Official Notice fail to teach or suggest a combination where at least some of the program data batch-downloaded into memory on the pump are individualized, patient-specific data items. Klein also fails to teach or suggest this aspect of the independent claims. Klein relates to integration of data collection devices (e.g. bar code scanners) with host software. Klein does not disclose batch-downloading into memory on the pump data items including individualized, patient-specific data items, or anything with respect to a pump for that matter. Therefore, no combination of the cited references or official notice will result in the claimed combination of elements.

Based on the above discussion, the applicant respectfully requests reconsideration and withdrawal of the pending rejection of independent claims 7, 10, and 16. Likewise, claims 8-9 depend from claim 7, claims 11-15 depend from claim 10, and claims 17-19 depend from claim 16. These claims inherit the elements of the independent claims from

which they depend, and therefore the applicant respectfully requests reconsideration and withdrawal of the pending rejection of these dependent claims as well.

**C. Claims 4 and 5**

Claims 4 and 5 stand rejected as being obvious under 35 U.S.C. § 103(a) over Peterson in view of Eggers as applied to claim 3, and further in view of “Acute Health Solutions.” The applicant respectfully traverses this rejection and does not concede the characterizations of the cited references or the pending application set forth in the office action.

Claims 4 and 5 depend from claim 1 and also require that at least some of the program data batch-downloaded into memory on the pump are individualized, patient-specific data items.

As an initial matter, claim 3 stands rejected as being obvious over Peterson in view of Eggers in view of Official Notice. The applicant therefore assumes that the Examiner incorporates the Official Notice into this rejection as well.

Second, and as discussed above, Peterson, Eggers, and the Official Notice fail to teach or suggest a combination where at least some of the program data batch-downloaded into memory on the pump are individualized, patient-specific data items. Acute Health Solutions also fails to teach or suggest these elements. Therefore, no combination of the cited references or official notice will result in the claimed combination of elements. The applicant respectfully requests reconsideration and withdrawal of the pending rejection of these claims.

**D. Claim 18**

In the Office Action, claim 18 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Peterson in view of Eggers, in view of Official Notice, and in view of Klein as applied to claim 17 above, and in further view of “Acute Health Solutions.”

As discussed above, Peterson, Eggers, the Official Notice, and Klein fail to teach or suggest a combination where at least some of the program data batch-downloaded into memory on the pump are individualized, patient-specific data items. Acute Health Solutions also fails to teach or suggest these elements. Therefore, no combination of the

cited references or official notice will result in the claimed combination of elements. The applicant respectfully requests reconsideration and withdrawal of the pending rejection of this claim.

**CONCLUSION**

In view of the foregoing remarks, the applicant respectfully requests withdrawal of the pending rejection and advancement of this application to issuance. The applicant also notes that there may be additional reasons that the claimed invention is patentably distinct from the cited references in addition to those raised in the above remarks. The applicant reserves the right to raise any such reason in the future.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned attorney at (612) 336-4608.

Respectfully submitted,

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